

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

MERCK EPROVA AG,

Plaintiff,

v.

BROOKSTONE PHARMACEUTICALS,  
LLC a/k/a ACELLA PHARMACEUTICALS,  
LLC, et al.

Defendants.

No. 1:09-CV-9684(RJS)(JCF)

**DEFENDANTS' OBJECTIONS TO DIRECT TESTIMONY OF IVAN T. HOFMANN**

Defendants, by and through counsel, submit the following evidentiary objections to the direct testimony affidavit of Ivan T. Hofmann (Plaintiff's Trial Exhibit No. 290).

<b><u>OBJECTIONABLE MATERIAL</u></b>	<b><u>OBJECTION(S)</u></b>	<b><u>RULING</u></b>
¶ 6: "In my opinion, the presence of Jubilant Pharmaceuticals ("Jubilant") in the market should not factor into the calculation of damages (as discussed more fully below). It is my understanding from Merck that the Jubilant products appear to infringe existing patents belonging to Merck and/or falsely represent the ingredients contained in their products. Thus, it is my understanding that the Jubilant products are subject to allegations of either patent infringement and/or false advertising claims by Merck. Accordingly, it is appropriate to exclude Jubilant in calculating damages."	Lack of foundation and personal knowledge (FRE 602)	Sustained ____
	Improper opinion, insufficient basis for opinion (FRE 702, 703)	Overruled ____
	Hearsay (FRE 802)	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
¶ 8: “Specifically, there is no evidence in the record to support a conclusion that the presence of the Acella generic products expanded the market for the prescription prenatal vitamin products at issue. Furthermore, because demand for prescription prenatal vitamins is driven by prescriptions written by physicians, the availability of lowered price alternative products is unlikely, on its own, to affect the prescription writing of physicians.”	Lack of foundation and personal knowledge (FRE 602)  Improper opinion (FRE 702, 703)  Affiant not designated as an expert on pharmaceutical markets and demand under FRCP 26  Argumentative	Sustained ____  Overruled ____  Overruled ____  Overruled ____
¶ 18: “One of Merck’s products, L-methylfolate (“L-5-MTHF”), is a source of folate, and marketed under the trademarked name Metafolin.”	Lack of foundation and personal knowledge (FRE 602)  Legal conclusion (states that Metafolin <i>is</i> L-5-MTHF)  Affiant not designated as an expert on folates or chemical nomenclature under FRCP 26  Cumulative (FRE 403)	Sustained ____  Overruled ____  Overruled ____  Overruled ____
¶ 21: “I understand that the Acella products at issue in this case include PNV-Select, PNV-DHA, and PNV-Omega, which are marketed as lower cost alternatives to Prenate Elite, Prenate DHA, and Prenate Essential, respectively. I understand that the Acella Products at issue contain the raw materials Xolafin and Xolafin-B, which Acella alleges are properly named L-5-MTHF.”	Lack of foundation and personal knowledge (FRE 602)  Improper opinion (FRE 702, 703)  Affiant not designated as an expert on folates or chemical nomenclature under FRCP 26  Assumes facts not in evidence (that Acella refers to Xolafin as L-methylfolate)  Cumulative (FRE 403)  Argumentative	Sustained ____  Overruled ____  Overruled ____  Overruled ____  Overruled ____

**OBJECTIONABLE MATERIAL**

¶ 22: “Merck has alleged that the Acella Products use the dietary ingredient D,L-5-MTHF and not the dietary ingredient L-5-MTHF. Further, Merck has alleged that through Acella’s product labels, product inserts, and marketing materials, the Defendants have falsely represented, and continue to falsely represent, that the Acella Products use the dietary ingredient L-5-MTHF. Merck has also alleged that Defendants have represented to pharmacists, physicians, pharmacy databases, consumers, the public, and the market that the Acella Products are generic versions of the Sciele Products.”

¶ 23: “I understand that the Sciele Products are prescription products that are not subject to approval by the FDA, but which are regulated by the FDA. I further understand that the Acella Products have been linked to the Sciele Products in First DataBank, Medispan, and other databases used by pharmacists and that this linking allows the Acella Products to be substituted at pharmacies for the Sciele Products. Therefore, the sales of Acella Products would have been sales of the Sciele Products but for the substitution. In addition, because Merck receives a 6 percent royalty on the net sales of the Sciele Products, any Acella Product sale has resulted in lost royalties to Merck.”

**OBJECTION(S)****RULING**

Lack of foundation and personal knowledge (FRE 602)      Sustained \_\_\_\_

Improper opinion (FRE 702, 703)      Overruled \_\_\_\_

Affiant not designated as an expert under FRCP 26

Cumulative (FRE 403)

Argumentative

Lack of foundation and personal knowledge (FRE 602)      Sustained \_\_\_\_

Improper opinion (FRE 702, 703)      Overruled \_\_\_\_

Affiant not designated as an expert on FDA issues, pharmaceutical databases, or pharmaceutical markets under FRCP 26

Cumulative (FRE 403)

Argumentative

## **OBJECTIONABLE MATERIAL**

¶ 38: “I understand that the Jubilant products may be substituted for the Sciele Products in some instances. However, based upon my understanding, discussions with Merck and its counsel, and review of documents, it is Merck’s belief that the Jubilant products appear to infringe existing patent rights belonging to Merck and/or falsely represent the ingredients contained in the products (Weibel Affidavit at ¶ 72). As such, the Jubilant products are subject to allegations of either patent infringement and/or false advertising claims. Given this understanding, excluding the Jubilant products from the calculation of damages is appropriate. Generally accepted practice and literature regarding the calculation of damages in intellectual property matters explains that excluding competitors that are believed to be infringing or on the market in some unsanctioned way should be excluded in determining damages.”

¶ 39: “I understand that Pamlab and Merck filed suit against Trigen Laboratories, Inc. (“Trigen”) which resulted in a resolution of the litigation between the parties. I understand from publicly accessible sources that Trigen is a subsidiary of Jubilant. I further understand that although to date no suit has been filed against Trigen with respect to Sciele products, the allegations with respect to the Trigen products that compete with Pamlab’s products would similarly apply to the Trigen products that compete with the Sciele

## **OBJECTION(S)**

## **RULING**

Lack of foundation and personal knowledge (FRE 602)

Sustained \_\_\_\_

Improper opinion, insufficient basis for opinion (FRE 702, 703)

Overruled \_\_\_\_

Affiant not designated as an expert on pharmaceutical databases or pharmaceutical markets under FRCP 26

Hearsay (FRE 802)

Relevance (FRE 402, 403)

Sustained \_\_\_\_

Lack of foundation and personal knowledge (FRE 602)

Overruled \_\_\_\_

Improper opinion, insufficient basis for opinion (FRE 702, 703)

Affiant not designated as an expert under FRCP 26

Assumes facts not in evidence

Hearsay (FRE 802)

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
Products.”		
¶ 40: “It would be inappropriate to reduce damages available to Merck because Jubilant is on the market. If Acella is found liable in this matter, Acella would be able to relieve itself from a portion of damages due to the presence of Jubilant products on the market (even though Jubilant is believed to be infringing and/or falsely advertising). If Jubilant were ultimately found liable for infringement and/or false advertising, Jubilant could potentially relieve itself from a portion of damages due to the presence of Acella Products on the market. Further, if Merck were to obtain judgment against Jubilant subsequent to this litigation, Merck could be unable to recover the lost profits to which it should have been entitled in this matter. This creates an economically inequitable result where both Acella and Jubilant could be found liable, yet Merck would receive an insufficient damages award due to the alleged actions of the others on the market. Dr. Boudreax’s damages theory which includes Jubilant would make it extraordinarily difficult, if not impossible, for Merck to recover its full lost profits.”	Lack of foundation and personal knowledge (FRE 602)      Sustained ____	
	Improper opinion, insufficient basis for opinion (FRE 702, 703)      Overruled ____	
	Affiant not designated as an expert under FRCP 26	
	Assumes facts not in evidence	
	Legal conclusion	
	Vague as to “economically inequitable” and “insufficient damages”	
	Speculation based on the affiant’s assumption that the outcome of non-existent litigation would favor Plaintiff	
	Argumentative	

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
¶ 42: “Dozens of prescription prenatal vitamins are on the market. Numerous branded prescription prenatal vitamins compete for time with physicians to detail aspects of their company’s products. In addition to prenatal vitamin representatives, women’s health physicians also are called upon by sales representatives for other drugs, contraceptives, etc. There is no evidence that (1) physicians would have awareness that Acella launched a lower cost version of Prenate products or (2) that the availability of the Acella product would change prescribing behavior by such physicians.”	Relevance (FRE 402, 403)  Lack of foundation and personal knowledge (FRE 602)  Improper opinion (FRE 702, 703)  Affiant not designated as an expert on prescription products or the knowledge and activities of physicians and pharmacists under FRCP 26  Hearsay (FRE 802)  Legal conclusion  Argumentative	Sustained ____  Overruled ____
¶ 42: “I further understand that Acella has admitted that it has no direct knowledge of any doctor or other person authorized to write prescriptions writing a prescription for the PNV Products.”	Lack of foundation and personal knowledge (FRE 602)  Improper opinion (FRE 702, 703)  Affiant not designated as an expert on prescription products or the knowledge and activities of physicians and pharmacists under FRCP 26  Mischaracterizes evidence ( <u>see</u> Spanier Trial Affidavit ¶ 14)  Assumes facts not in evidence concerning prescriptions for PNV ( <u>see</u> Spanier Trial Affidavit ¶ 14)	Sustained ____  Overruled ____

<u>OBJECTIONABLE MATERIAL</u>	<u>OBJECTION(S)</u>	<u>RULING</u>
¶ 43: “A conclusion that the Acella product(s) expanded the market is simplistic and erroneous because it ignores how demand for prescription prenatal vitamins is created and fails to address numerous other factors which likely caused the increase in sales.”	Lack of foundation and personal knowledge (FRE 602)  Improper opinion (FRE 702, 703)  Affiant not designated as an expert on pharmaceutical markets under FRCP 26  Argumentative	Sustained ____  Overruled ____  Overruled ____  Overruled ____
¶ 47: “In this particular case, for example, it would be inappropriate to use the legal fees associated with this and related litigation involving Acella to reduce Acella’s potential disgorgement liability. It would be unreasonable to deduct legal fees for conduct found to be unlawful.”	Lack of foundation and personal knowledge (FRE 602)  Improper opinion, insufficient basis for opinion (FRE 702, 703)	Sustained ____  Overruled ____
¶ 48: “A mere pro-rata allocation of indirect expenses to the Acella Products is insufficient without an understanding of the composition of such expenses. I am not aware of any evidence that Acella has produced that establishes the composition and applicability of the claimed expenses.”	Lack of foundation and personal knowledge (FRE 602)  Improper opinion, insufficient basis for opinion (FRE 702, 703)  Argumentative	Sustained ____  Overruled ____  Overruled ____

Respectfully submitted,

**MILLER & MARTIN PLLC**

By: *s/ C. Celeste Creswell*

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